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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,190	04/10/2001	Katsuya Matsuda	MATSUDA 13	4190

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EXAMINER

PULLIAM, AMY E

ART UNIT PAPER NUMBER

1615

DATE MAILED: 10/21/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/807,190

Applicant(s)

MATSUDA ET AL.

Examiner

Amy E Pulliam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2002.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 11-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Receipt of Papers

Receipt is acknowledged of the Declaration and Amendment C with Extension of Time, all received by the Office on June 26, 2002.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by any of US Patents 5,496,545 or 6,083,495 or 5,667,775 to Holmes-Farley *et al.* (Holmes) (As the three specifications are almost identical, the examiner will rely on the column and line numbers of the '545 patent to simplify the following rejections). Holmes disclose phosphate binding polymers used to remove phosphate from the gastrointestinal tract. Holmes also teach that the polymers of their invention may be cross-linked with a cross-linking agent, such as epichlorohydrin (c 2, l 2-5). Furthermore, as admitted by applicant in claim 10, Holmes discloses the same poly(allylamine/epichlorohydrin) polymer claimed by applicant (c 8, l 15). Additionally, Holmes teaches that the composition of their invention can be administered in any well known, oral, pharmaceutical method, including tablet form (c 17, l 38).

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Applicant's arguments have been fully considered but are not found to be persuasive.

Applicant has submitted a declaration by Katsuya Matsuda. The examiner finds the declaration unpersuasive for several reasons. First, the declaration, as well as the experimental data in the specification fail to establish 1.24 as the critical upper limit, or 1.18 as the critical lower limit, of the specific gravity. More specifically, there is no data which has a 1.18 or as 1.24 value for the specific gravity.

Second, the information provided in the declaration is not sufficient because there are not amounts given for the polymer, solvents, or cross linking agents. Therefore, there is no data to establish that the results obtained accrue solely on the basis of the solvent mixture. More specifically, there is no indication that the only changing variable is the solvent mixture. The amount of components used could also be varied.

Lastly, the declaration is not commensurate in scope with the instant claims. The claims allow a specific gravity of between 1.18 and 1.24. However, the data presented in the specification only ranges from 1.2044 to 1.2174. Therefore, the unexpected results demonstrated only pertain to this more specific range. Applicant has provided no evidence that unexpected result occur outside this specifically discussed range.

For these reasons, the examiner still finds the above rejection appropriate, and it is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9, and 11-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of the Holmes patents discussed above, and in view of the following comments. Holmes is discussed above as teaching a pharmaceutical tablet comprising applicant's claimed polymer. Holmes does not teach the specific gravity ranges claimed by applicant. However, applicant himself states, in instant claim 10, that the polymer used in the instantly claimed formulation is the one described in the Holmes patent. Therefore, applicant himself has acknowledged that the two polymers are the same.

Additionally, Holmes does not specifically teach a particles size for the polymer, once it is incorporated into the tablet formulation. However, Holmes does teach a method of producing granulates of the polymer (c 8, l 30). Additionally, in the '495 patent, which claims the method of making the pharmaceutical composition, column 20, claim 8 clearly teaches the formation of particles. It is the position of the examiner that it is within the skill of the art to manipulate a specific particle size as part of the process of normal optimization. Absent a showing of criticality, it is the position of the examiner that this limitation is obvious to one of ordinary skill in the art.

Holmes also teaches that in making the pharmaceutical composition, the polymeric phosphate binder may be mixed with a carrier, diluted by a carrier, or enclosed with a carrier (c 17, l 28-35 of the '545 patent). Holmes does not go into specifics regarding what the carrier can be. However, it is the position of the examiner that this general teaching would lead one of ordinary skill in the art to combine any well known carrier with the phosphate binding polymer,

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in order to make a successful pharmaceutical composition. Additionally, absent any evidence to the contrary, it is the position of the examiner that crystalline cellulose and hydroxypropyl cellulose are both very well known tablet excipients, and would be obvious to use in a pharmaceutical tablet composition. Furthermore, it is also the position of the examiner that the specific excipients used is not the critical aspect of applicant's invention.

Claim 11 is a product by process claim. According to the MPEP section 2113, "even though product by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production, If the product in the product-by-process claim is the same or obvious from a product of the prior art, the claim is unpatentable even though the prior art was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed.Cir. 1985).

Lastly, the *Holmes* also renders applicant's process of making claims obvious. Us Patent 6,083,495 specifically claims the method of making the pharmaceutical composition. This method entails cross-linking the polymer, followed by mixing the polymer with a carrier. As discussed above, it is the position of the examiner that the specific carrier chosen is a limitation which would be obvious to one of ordinary skill in the art.

One of ordinary skill in the art would have been motivated to create a pharmaceutical tablet, comprising the specific phosphate binding polymer and a well known tablet excipient, based on the teachings of *Holmes*. The expected result would be a successful tablet formulation which is successful in removing phosphate from the gastrointestinal tract. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

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Applicant's arguments have been considered and are not found to be persuasive for the reasons discussed above. This rejection is maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is (703) 308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone numbers for the

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organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

A. Pulliam
Patent Examiner
Art Unit 1615
October 18, 2002


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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